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The Influence of Current Judicial Doctrines on the Cost of Purchasing Health Care

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A Report of the
Advisory Council
on Social Security

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

Five sorts of litigation against the health care industry—physicians, hospitals, health plans, insurers, and product manufacturers—bear significantly on the costs of obtaining health care.

I.

Suits over coverage under contracts of health insurance involve, in the main, a contention by the insured that a treatment is "reasonable and necessary" to alleviate his ailment; the insurer contends, to the contrary, that it falls under a general exclusion for treatments that are "experimental or investigational." Although the test of these contentions is current medical practice—whether a treatment is accepted within the profession—some courts have decided these cases on the basis of evidence that the treatment, although not accepted, is effective.

An insured may also, in some cases, avoid the issue altogether by suing for a preliminary injunction. If he shows that a refusal to cover treatment would cause him irreparable harm, and that he has at least some argument that the treatment is not experimental (or is effective), the court may require the company to pay for the treatment pending the outcome of the litigation.

The insured is aided by several legal doctrines that read insurance contracts for the benefit of the insured, and construe ambiguities against the insurer.

As a result of a major shift, in 1989, in the doctrines applied by the Federal courts to suits under the Employment Retirement Income Security Act, the

Federal courts now decide ERISA suits much like State courts acting under State law.

There is no way in which an insurance company can readily anticipate these decisions, which tend to extend coverage for the most expensive technologies, except by building large margins into its premium structure. This has two effects: (1) it increases the costs of health care, as a share of the gross national product, by extending existing insurance to additional services; and (2) it may reduce the availability of health insurance, thereby tending to lower the national costs of health care, as a share of the GNP, because some health care services will no longer be available to persons who can no longer afford to pay for them.

Note that the increased insurance premium does pay for a real economic good: broader coverage. Therefore, subject to the fluctuations of supply and demand (to the extent they operate in the health care market), coverage decisions should be relatively neutral in their effect on the base price of services.

II.

Malpractice claims are based on a patient's contention that the negligent failure of his health care provider to adhere to current standards of medical care—usually an error in diagnosis, evaluation and treatment, prescribing and dosing, procedure, or communication—caused the adverse outcome of his medical treatment.

The most significant malpractice issue of recent years has involved the question of a physician's liability when, against his better judgment, he takes

a course of action directed under a system of managed care. In a leading case, the California Court of Appeals upheld such a direction as within acceptable medical standards, even though in the circumstances it led to patient injury. But the court observed that a third-party payer would be liable for erroneous medical decisions resulting from its actions, and a physician cannot shift legal responsibility for his patient's welfare to a third-party payer by complying with the directives of a cost containment program.

The 1980's saw a vast increase in the frequency and size of malpractice claims, engendering what has been described as a "crisis" in the cost of professional liability insurance. In response, some states enacted statutes to limit the amount of recovery in malpractice claims (or cap non-economic damages, such as for pain and suffering), require that the claims be submitted to a pretrial panel, require awards to be offset by insurance, or shorten the period during which a claim may be filed after the injury. Several of these statutes have been successfully attacked on the constitutional ground of equal protection, i.e., that they arbitrarily create a disfavored class of litigants.

The effect of malpractice decisions has been to drive up the costs of professional liability insurance premiums at an average annual rate, since 1985, of 13.9% for all physicians, with the average nationwide professional liability premium in 1989 at $15,500. This represented, for all self-employed physicians, 4.9 percent of total practice revenues.

Within this average, the distribution moves from a high of $37,000 for obstetricians and gynecologists (9% of practice revenues) to a low of $5,500 for pathologists (2.1% of revenues). But evidence suggests that physicians have not been able to pass all of these increases on to their patients through increased fees.

In devising a legislative approach to the question of limiting the effect of malpractice awards on the cost of health care, the policy maker must distinguish between two components of an award: direct damages and consequential damages.

Consequential damages—pain and suffering, punitive damages, loss of consortium, and the like—are not to compensate the claimant for economic losses. Their size is necessarily arbitrary. It can be argued that a rationale for limiting their size—albeit by another arbitrary amount—is that the health care system can no longer afford the costs of what, to a plaintiff who is, in any event, to be compensated for real economic loss, is a financial windfall.

Direct damages—actual economic loss or additional expense that malpractice inflicts on an individual—raises a policy issue of a different sort. Beyond the expense to an individual in obtaining health care, there is the expense that the care may inflict upon him. A malpractice award of direct damages is intended to compensate him for this economic loss by spreading it, through malpractice premiums, to the health care system at large. Here, a decision to limit the size of the award must be based on the more difficult judgment that the public interest requires an individual personally to bear some significant portion of that loss.

Although the components of a malpractice award are reasonably clear in a malpractice case, they are far more difficult to distinguish in the mass of settlements that never reach the courts. If one disregards the outliers, consequential damages, in the average case not involving permanent loss of earnings, are between three and four times the amount of direct damages.

Finally, in estimating the costs of judicial doctrines in professional liability cases, there is the cost of "defensive medicine." Because professional

standards are vague, and physicians are sometimes confused as to the standards to which a court may hold them, there is a tendency in the medical profession to employ procedures that a physician considers necessary solely to avoid the threat of malpractice litigation.

Inasmuch as the standards that a court applies in a malpractice case are those, insofar as they can be ascertained, of the medical profession itself, some portion of this "defensive medicine" is likely to be unnecessary to protect the physician. Another portion, although perhaps thought unnecessary by the physician employing it, is considered good and desirable medical practice by some sample of his peers.

The problem for physicians, as Clark Havighurst has pointed out, is that the courts, by judicial fiat, have imposed upon them, regardless of the individual circumstances of the physician or his patients, the highest standards of the profession.

How much of defensive medicine is truly unnecessary to protect against a malpractice action, and how much cost that adds to patient charges, is not known.

III.

Litigation over injury caused by prescription drugs and medical devices is governed by State law that, in general, imposes an absolute liability on manufacturers for "defective" products, i.e., products that cause unanticipated and unwarned-of injurious effects. The volume of these cases is dramatically affected by the major manufacturer/single product "epidemic" cases, such as the litigation over the Dalkon Shield and Bendectin. But even if these are

disregarded, the number of health product liability cases grew steadily throughout the 1980's at a rate that far exceeded that for other product liability litigation.

One estimate puts the cost of medical device product liability at about four percent of the sale price of every medical device, compared to an earlier estimate for manufacturing firms generally of less than one percent.

The major cost of product liability to the health care system is probably the hidden cost: high-risk products that are not developed because the dangers of litigation exceed the potential for profit.

IV.

Litigation to terminate medical treatment has burgeoned in response to the growing ability of medical science to prolong life beyond the desires of those receiving care. In general, the present state of the law in this area supports the unqualified right of a competent individual to refuse medical care, including artificial nutrition and hydration, even if the individual is not suffering from a terminal illness.

In the case of an individual who is not competent, the usual practice is to permit a guardian or family member to exercise the right on his behalf. But the standard is one of "substituted judgment." That is, the court must be persuaded that the decision to withdraw care is one that the individual himself would have taken if he were competent. In at least one jurisdiction, Missouri, this standard can only be met by clear and convincing evidence of intentions expressed by the individual while competent. Other jurisdictions are generally less exacting.

Because of the growth of the aged population—68 million people will be over age 65 by the year 2040, and 12.2 million will be over age 85—and the exponential increase in medical costs as individuals enter the last decades of life, the exercise of the right to refuse medical care will bear increasingly on the national costs of health care. How much its exercise will offset the rising expense of new technology to prolong life even further is speculative.

V.

Antitrust suits to prevent or reverse mergers and acquisitions by health care providers are usually conducted by the Justice Department and the Federal Trade Commission, although private action is not unknown.

The governing law is complex, and is summarized below in the pertinent section of this report. The basic objective of these cases is to interdict a provider's acquisition of "market power" (i.e., the ability of a seller profitably to restrict output and raise prices above competitive levels without losing a large part of its business).

The economic implications for health care providers are unclear. Certainly, antitrust actions interfere with efficiencies in service delivery that could reduce both the price of services and the costs of the health care system. But they also interfere with market concentration that, at least in the opinion of the Justice Department, the Federal Trade Commission, and the courts, would increase those prices and costs.

INTRODUCTION

National expenditures for health care have consistently outpaced the consumer price index. The Health Care Financing Administration estimates that from 1985 through 1989, when the annual rate of inflation in the United States ranged between two and five percent, the average annual growth of health care expenditures was nearly 10 percent.[1] In 1990, health spending increased "more than twice as fast as the 5.1 percent growth rate of the economy as measured by the GNP."[2]

This report examines one major influence on health care costs—judicial decisions in litigation against the health care industry: physicians, hospitals, health plans, private insurers, and product manufacturers. These decisions influence the ways in which physicians and other health care providers practice their profession, the premiums and coverage of health care insurers, the cost of pre-payment health care plans and the services they offer, the health care options, if any, employers offer their employees, and the cost of drugs and medical devices.

[1] Health Care Financing Review/Winter 1990/Volume 12, Number 2, Table 11. The HCFA Office of the Actuary, Office of National Health Statistics, estimates the increase for 1990 over 1989 to be 10.5 percent (unpublished table supplied by HCFA).

[2] Release of the Department of Health and Human Services, Wednesday, October 2, 1991, HHS News, p. 1, citing information announced by HHS Secretary Louis W. Sullivan.

Although private persons may and do sue health care providers under the antitrust laws,[3] the primary burden of enforcing them lies with the Justice Department and the Federal Trade Commission. Their enforcement—and the shadow cast by the threat of their enforcement—directly limits private action to improve the efficiency of health care services. The report concludes with a brief examination of the possible opposing effects of the antitrust laws on health care costs.

The report examines decisions in five areas:

- Decisions interpreting the coverage of health insurance contracts, which influence health insurance premiums.

- Decisions on malpractice claims, which affect malpractice insurance premiums and indirectly influence health provider charges.

- Decisions in product litigation cases, which indirectly influence the price of drugs and medical devices.

- Decisions in cases in which a patient or his family seeks to terminate care, which primarily affect expenses for care of the terminally ill and patients in irreversible coma.

- Decisions in antitrust actions, which interdict hospital mergers or other provider actions to consolidate services.

[3] See, e.g., Nelson and Bowman v. Monroe Regional Medical Center, 925 F. 2d 1555 (1991) (A private party was found to have grounds to challenge a merger of health care providers that, she alleged, diminished her access to health care). Section 4 of the Clayton Act, 15 U.S.C. 15, provides, "... any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor."

Not every such decision increases health care costs. And, when one does, there is usually no way to quantify its effect. What this report attempts to do instead is to describe the judicial doctrines that underlie these decisions and assess their general cost effects. Cost data are provided where available.

This report does not offer a definitive analysis of each question discussed; nor does it try to evaluate the propriety of the policies involved in those questions or the decisions taken. Its purpose is to present the cumulation of various judicial activities and raise the issue of their impact on health care costs.

COVERAGE LITIGATION[4]

When Is Treatment Investigational?

Under a health care insurance agreement,[5] the insurer agrees, in general language, to pay for a treatment ordered by a physician, and commonly and customarily recognized throughout the medical profession as appropriate—that is, reasonable and necessary—in the treatment or diagnosis of sickness or injury (i.e., a treatment in accordance with generally accepted standards of medical practice). The agreement will then exclude some treatments specifically: either because they would otherwise fall within the general coverage language, but the insurer does not wish to pay for them, or to emphasize that the insurer believes them to be excluded by the general coverage language.[6]

Almost all health care insurance agreements explicitly exclude from coverage a treatment that is experimental, or otherwise furnished mainly for the

[4] This portion of the report relies on research and analysis performed by Jonathan G. Rose, a law student at Catholic University, and contained in an unpublished paper, "Health Insurance Contracts: The Need for a Uniform Understanding of What Constitutes Experimental Medicine."

[5] For the balance of this part of the report, references to a "health insurance agreement," "health insurance policy," "insurance contract," or "insurer" should be taken to include agreements with health maintenance organizations, preferred provider option plans, and other provider groups that offer health plans that guarantee delivery of health care services in exchange for a prepayment.

[6] Sweeney v. Gerber Medical Benefits Plan, 728 F. Supp. 594 (D. Neb. 1989) (court held that use of HDCT-ABMT was not covered, particularly inasmuch as the physician had required the plaintiff, before use of the drug, to sign a consent form explicitly acknowledging that the treatment was investigational). But note that HDCT-ABMT has been found to be covered in other cases, e.g., Pirozzi v. Blue Cross Blue Shield of Va., 741 F. Supp. 586, 588 (E.D. Va. 1990) (contract excluded treatments that were "experimental or clinical investigative treatments...of no scientifically proven value and those not in accordance with generally accepted standards of medical practice.")

purpose of medical or other research; or is not reasonable and necessary for the diagnosis or treatment of an illness or injury.[7]

Most of the litigated disputes between an insurer and the insured over whether a particular treatment is covered under a health insurance policy or by a health care plan are over the question of whether a course of treatment is "reasonable and necessary," or whether it is "experimental" or "investigational."

A claimant must persuade the court that a treatment meets the "reasonable and necessary" standard, usually by producing medical witnesses who will testify to the general acceptance of the treatment within the medical profession. But this is not possible in cases concerning experimental investigative therapy. Instead, claimants seek to persuade the court that the treatment is effective.

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[7] Blue Cross and Blue Shield of Virginia provides in its experimental exclusion, for example, that coverage excludes "experimental or clinical treatments that have no scientifically proven value and those not in accordance with generally accepted standards of medical practice." Pirrozi v. Blue Cross and Blue Shield of Virginia, 741 F. Supp. 586, 588 (E.D. Va. 1990). Another example of exclusionary language: "no insurance is afforded...as to charges...for care, treatment services or supplies which are not reasonably necessary for the treatment of the injury or disease concerned." Dallis v. Aetna Life Ins. Co., 574 F. Supp. 547 (N.D. Ga.) aff'd. 768 F. 2d 1303 (11th Cir. 1983) (plaintiff sought coverage for immuno-augmentative therapy, a procedure where factors within the patient's blood are strengthened by injections of deblocking protein and tumor antibodies, in an attempt to cure her cancer after all other conventional techniques had failed).

This is also the approach of the Health Care Financing Administration in dealing with reimbursement questions under Medicare:

> Medicare does not pay for services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury. These services include drugs or devices that have not been approved by the Food and Drug Administration ("FDA"), medical procedures and services performed using drugs or devices not yet approved by the FDA, and services not considered safe and effective because they are experimental or investigational. [Department of Health and Human Services Medicare Handbook 20 (1990) (HCFA 10050)]

Sometimes this approach prevails, even where the treatment is plainly not accepted by the medical community: for example, the treatment of cancer with vitamins and laetrile.[8] Sometimes this approach fails.[9]

Problems for Insurers Caused by Contracts of Adhesion

A claimant against an insurer is aided by a judicial doctrine developed to help equalize the struggle between individual claimants and corporate defendants. An insurance contract is what the courts term a "contract of adhesion." This means that it is a standardized offer of goods and services essentially on a "take it or leave it" basis: a basis that does not afford the consumer a realistic opportunity to bargain.[10] Once a contract is found to

[8] See, e.g., Shumake v. Travelers Ins. Co., 147 Mich. App. 600, 383 N.W.2d 258 (1985), where the health insurance agreement provided that it would cover "all prescriptions and treatments recommended by the attending physician," and the attending physician recommended laetrile. The court found for the plaintiff, notwithstanding evidence presented that the Food and Drug Administration did not consider laetrile safe or effective, and that there was a broad consensus within the medical community in support of the FDA position.

[9] See, e.g., Free Travelers Ins. Co, 551 F. Supp. 554 (D.Md 1982), in which plaintiff disregarded advice of his Johns Hopkins physicians to undergo chemotherapy, and instead, on the advice of a general practitioner, sought holistic treatments consisting of vitamins and laetrile, for which he sought reimbursement from his insurer. At the trial, plaintiff supported his claim that the treatments were "reasonably necessary" solely with an affidavit of the attending nutritionist at the holistic center. The court approached the issue entirely on the question of the relative effectiveness of the alternative treatments and found for the insurer.

[10] BLACK'S LAW DICTIONARY 38 (5th ed. 1979) defines an adhesion contract as a "[s]tandardized contract form offered to consumers of goods and services on essentially a 'take it or leave it' basis without affording [the] consumer a realistic opportunity to bargain and under such conditions that the consumer cannot obtain the desired product or services except by acquiescing in [the] form contract."

be one of adhesion, the courts interpret the contract for the benefit of the insured.[11]

For example, a contract covering ". . . charges incurred by a Member for necessary services performed or prescribed by a licensed Doctor of Medicine for an illness . . .," but not containing an exclusion for experimental treatment, was held to cover non-standard treatment for Down's Syndrome. The court concluded that the term "necessary" did not have "an exact definition." Accordingly, "we must liberally construe it for the benefit of the party insured . . . ."[12]

The insured is also assisted by another doctrine of law: one that does not depend upon the finding of a contract of adhesion. This doctrine, *contra proferentium*, holds that all ambiguities found in a contract should be interpreted against its drafter.[13]

These doctrines—the first causing insurance contracts to be interpreted for the benefit of the insured, the second causing ambiguities to be construed against the company—provide the court little basis on which to rule against the insured. The insurer's use of such terms as "reasonable and necessary" to

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[11] "If the insurer deals with the public upon a mass basis, the notice of noncoverage of the policy, in a situation in which the public may reasonably expect coverage, must be conspicuous, plain and clear." Ponder v. Blue Cross of Southern Cal., 145 Cal. App. 709, 713, 193 Cal. Rptr. 632, 636 (1983).

[12] Fassio v. Montana Physicians Service, 170 Mont. 320, 553 P.2d 998 (1976). The court went on to say, "If Montana Physician's Service wishes to exclude or limit the risk contracted for, then let them do so in words that leave no doubt. The law is clear in this jurisdiction that exclusion clauses are construed narrowly against the insurer."

[13] See, e.g., Van Vactor v. Blue Cross Ass'n, 50 Ill. App. 3d 709, 365 N.E. 2d 639 (1977) (ordering coverage for dental surgery because the contract was ambiguous about whether medical necessity was to be determined by the dentist or the insurer); Aetna Life Ins. v. Sanders, 127 Ga. App. 352, 193 S.E.2d 173 (1972) (classifying exogenous obesity as a "disease" so that beneficiary could obtain coverage for expensive surgery).

describe medical procedures covered by the contract are vague. But given the "adhesion" and *contra proferentium* doctrines, the courts will hold the insurer to a standard of clarity, in the expression of an exclusion, that no insurer can meet without itemizing discrete treatments.

As a result, insurers cannot estimate, in advance, financial exposure for treatments that, at the time of issuance of a contract, either did not exist or were thought by the insurer to be investigational. To protect against these unanticipated losses, insurers build into their premiums a significant margin for error.

The Use of Injunctive Relief to Avoid the Investigational Exclusion

In some cases, a claimant will sue to obtain a preliminary mandatory injunction to require the insurer to pay for a medical treatment that the insurer has informed the claimant is beyond the scope of coverage.

A court issues a preliminary injunction to stabilize a controversy, pending the outcome of the litigation. The courts consider it an extraordinary remedy, and require a plaintiff seeking injunctive relief to demonstrate that the plaintiff will suffer irreparable harm if the injunction is not issued. Generally speaking, this means that the claimant must show that he is threatened with something more than a merely pecuniary loss.

On this standard, a court granted a preliminary injunction on testimony of the plaintiff's physician that the plaintiff, who was suffering from an advanced stage of thyroid cancer and sought treatment with interleuken II, would:

> . . . suffer irreparable harm, either in the form of accelerated death or grave illness, if he is not treated with one of the very few drugs which holds out any hope to plaintiff of respite from his rare cancer.[14]

The court balanced the loss of money to the insurer, should it ultimately prevail, against loss of life to the plaintiff.

If the claimant shows irreparable harm, the court then proceeds to determine if the injunction should be issued. The claimant has now obtained a considerable advantage, because the court will not rule, at this stage of the litigation, on the insurer's position that the treatment is investigational. That is a matter to be decided by the trial. For the injunction to issue, the court need only conclude that the claimant, having shown the risk of irreparable injury, has also demonstrated either:

- a likelihood of success on the merits, or

- sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardship tipping decidedly toward the party requesting the preliminary relief.[15]

The court also will examine the insurer's contention that the treatment is investigational to assure itself that at least some basis exists in support of the claimant's argument that the treatment is not investigational (or, depending upon the court's legal orientation, that the treatment may be effective).

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[14] Gaffney v. Kaiser Foundation Health Plan of the Northeast, 7 E.B.C. 2090 (S.D.N.Y 1986) (plaintiff sought injunction to force insurer to pay for treatment of an advanced stage of thyroid cancer with interleuken II), at 2091.

[15] Gaffney v. Kaiser Foundation Health Plan of the Northeast, op. cit. note 14, at p. 2091, citing Jackson Dairy Inc. v. H.P. Hood & Sons, Inc., 596 F.2d 70, 72 (2d Cir. 1979).

If the defendant insurer ultimately prevails at trial, plaintiff will be legally obligated to reimburse it for the costs of the treatment that the injunction forced the insurer to provide. For this reason, the court may require plaintiff to post bond, but only if it determines that plaintiff can afford to do so.[16]

For many claimants—those who can afford neither the treatment nor the bond—the litigation is successfully concluded at this point. By the time, often several years hence, that the case comes to trial, the claimant may either be cured or deceased.

The Employment Retirement Income Security Act

The Employment Retirement Income Security Act ("ERISA"),[17] although primarily concerned with pension plans, also covers employee welfare benefit plans. These are employer-sponsored programs that provide cash benefits or medical care, often through health insurance plans the purchase of which is made, or arranged for, by the employer.

Although ERISA is Federal law, and explicitly preempts conflicting State law,[18] there is no legal bar to State courts deciding ERISA claims. In

[16] Gaffney v. Kaiser, op.cit. note 14. "However, based upon evidence concerning Gaffney's financial capabilities, the Court determines that Gaffney will be able to post a bond which will give defendant some security, in the event it ultimately prevails. Gaffney is directed to post a bond for $10,000 as security to the defendant . . . ."

[17] Public Law 93-406, 88 Stat. 829, 29 U.S.C. 1001 et. seq.

[18] Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41 (1987). The Supreme Court's decision was based on §514(a) of ERISA, which provides, "[e]xcept as provided . . ., the provisions of this subchapter . . . shall supersede any and all state laws insofar as they may now or hereafter relate to any employee benefit plan." Id., at 45.

practice, however, these cases are invariably decided in Federal district courts, either because a claimant has filed suit in a district court or, if he has filed in State court, the defendant has exercised its right to remove the case to the district court.

Until 1989, a case filed in district court was decided under a doctrine that greatly favored the insurer. To understand that doctrine, it must be remembered that before the advent of health care litigation under ERISA, the usual ERISA case involved the distribution of benefits under a pension plan. The claimant, in that case, was (or argued that he was) a beneficiary of the plan. The defendant was the fiduciary administering the plan. It is not surprising that, in interpreting a plan agreement under ERISA, the Federal courts would therefore look to general principles of the law of trusts. And, in doing so, it applied the doctrine that the trustee's determination is to be upheld unless found arbitrary and capricious.

This doctrine became difficult to support, however, in cases in which the employer, itself, was the trustee. Faced with just such a palpable conflict of interest, the Supreme Court, in a landmark case against the Firestone Tire and Rubber Company,[19] held, in February 1989, that the Federal district court must make an independent ("de novo") judgment as to the meaning of the terms of the plan.

This reasoning necessarily applies to litigation over health plan coverage, because the functional equivalent of the "trustee" in the ERISA pension fund context is the health plan administrator—often the company offering the coverage. When the plan administrator denies coverage, in that situation, it is acting in its own financial interest.

[19] Firestone Tire and Rubber Co. v. Bruch, 489 U.S. 101 (1989).

The result of the Firestone case has been that almost every ERISA welfare benefit case has since been decided in favor of the participant who had been denied coverage.[20]

Cost Implications

Coverage decisions operate on the costs of specific health care insurers and health plans and, by extension, on the costs of health care insurers and health plans generally.

It seems apparent from the cases cited in support of the preceding discussion that the standard exclusion for care, treatment services, or supplies that "are not reasonably necessary for the treatment of the injury or disease concerned,"[21] or for "surgery or medical treatment which is experimental in nature or which does not constitute accepted medical practice,"[22] does not adequately address the evolution of modern medical practice. Insurance contracts can no longer be priced with the protection formerly offered by the contractual understanding. Thus, judge-made insurance, of the kind described, has a:

> . . . particularly strong impact on prices because it tends to extend coverage only for the most expensive technologies. . . . . The magnitude of the price increase depends on whether the insurers elect

[20] See Pirozzi v. Blue Cross Blue Shield of Va., 741 F. Supp. 589 (E.D. Va 1990), Whittington v. Blue Cross Blue Shield of Md., 757 F. Supp. 661 (D. Md. 1991). But see Sweeney v. Gerber Products Co. Medical Benefits Plan, 728 F. Supp. 594 (D. Neb. 1989) (holding that HDCT-ABMT was experimental and therefore not entitled to coverage).

[21] Dallis v. Aetna Life Ins. Co., op.cit., note 7.

[22] Fassio v. Montana Physicians' Service, op.cit. note 12.

to continue coverage for the technology at issue. If they elect to continue coverage, they must raise the price of insurance to reflect the cost of the technology and the likelihood that it will be used.[23]

No doubt an insurer can enforce contract exclusions for therapy described explicitly: say, immuno-augmentative therapy, laetrile treatments, liver transplants, and so on. But the more specific the contract, the greater prospect that the courts will find that treatments not specifically excluded are included.

Therefore, the general trend of court decisions on the scope of coverage of health care insurance contracts is necessarily to increase costs. That is, a coverage issue normally comes to the court essentially in one posture: an insurance company or provider has refused to pay for, or provide, an item of health care on the ground that the agreement between the claimant and the company does not cover the item.[24]

The court's decision for the claimant increases the insurer's costs and, indirectly, the costs of health insurance; a decision for the defendant company maintains the status quo. It does not lower costs.

[23] Kalb, "Controlling Health Care Costs by Controlling Technology: A Private Contractual Approach, 99 Yale L.J. 1109, 1118 (1990).

[24] This report does not discuss the occasional case in which the only issue is whether the claimant had a valid agreement with the company. Cases of this kind present contract issues of no special significance to the level of health care costs.

If a court decides that a treatment is covered, this sets in motion two opposing trends.[25]

On the one hand, the decision tends to increase the aggregate cost of health care by extending existing insurance to health care services not previously available under it. Yet, by indirectly increasing the cost of insurance coverage, the decision works to reduce the availability of health insurance, with uncertain effects on those aggregate costs.[26]

There is need for a research agenda to develop satisfactory data to allow one to quantify these costs.

Benefits to Patients

The preceding discussion has focused on the tendency of coverage decisions to increase health costs. It makes no attempt to evaluate a countervailing intangible.

The increased costs that a court imposes on the insurer through a coverage decision for the claimant buys what the claimant believes to be a benefit. And, in fact, the judicial extension of insurance coverage to a new therapy may, if the therapy is effective, forestall or eliminate the claimant's need for

[25] The determination that a medical procedure is reasonable or necessary, when made by a federal court with respect to the Medicare program, or a state or federal court with respect to the Medicaid program, also has significant cost effects on state and federal expenditures for health care. These are outside the scope of this report.

[26] The decision may also have the effect of shifting some portion of health care costs from the private to the public sector, as Medicaid and state medical assistance programs are called upon to meet the costs of formerly insured individuals who now spend down into eligibility.

costly future medical treatment. Therefore, a coverage decision can, in particular cases, work to reduce costs in the long run.

MALPRACTICE LITIGATION

Malpractice, In General

This section of the report considers the economic impact of judicial decisions on malpractice claims, and related conceptual issues. The word "malpractice" generally refers to a judicial determination that an adverse outcome of medical treatment resulted from a negligent, or possibly willful, failure to adhere to current standards of medical care.[27] The essential judicial doctrine is settled:

> The general rule applicable to an award of damages in a medical malpractice action, apart from statutes limiting such damages, is that one who has been injured by the negligence of a physician or surgeon in the course of treatment or an operation is entitled to recover compensatory damages. While the amount of such damages is a question for the jury where the law provides no precise legal rule of measurement, the court may interfere if the amount allowed is inadequate or excessive. Punitive damages may be awarded in malpractice actions where the negligence is wanton or gross. And again, the amount is generally left to the discretion of the jury, having regard for all the circumstances of the particular case. [footnotes omitted][28]

[27] This is the definition used by the Task Force on Medical Liability and Malpractice of the Department of Health and Human Services in its Report of August 1987, at pp. 6-7.

[28] Kristine Cordier Karnezis, J.D., "Annotation: Validity and Construction of State Statutory Provisions Relating to Limitations on Amount of Recovery in Medical Malpractice Claim and Submission of Such Claim to Pretrial Panel," 80 A.L.R. 3d 583 (1990), at 2A.

For analytical purposes, most malpractice can be classified into one of five broad categories:[29]

- errors in diagnosis;
- evaluation and treatment;
- prescribing and dosing;
- procedural complications; and
- faulty communications.

A trial on a medical liability claim is, generally speaking, a factual inquiry to establish the customary practice of physicians with respect to the treatment (or lack of treatment) for the injury, illness, or condition that gave rise to the claim, and to determine if, and to what extent, the health care provider departed from that practice.[30]

[29] The categories are taken from a survey conducted by Wu, Folkman, McPhee, Lo, "Do House Officers Learn from Their Mistakes?" 265 JAMA 2089-2094 (1991). The authors surveyed 254 interns and residents at three academic internal medicine training programs through an anonymous questionnaire. Replies were received from 114. Although the survey was limited to internal medicine house officers, the breadth of the categories seems sufficient to embrace malpractice by other kinds of physicians as well.

[30] Cases dealing with the excessiveness or adequacy of damages awarded for personal injuries in different factual circumstances are collected in the annotations listed under the title "Excessive or Inadequate Damages" in the ALR Quick Index, 2d ed.

The Role of Third-Party Payers

The most significant malpractice issue of recent years has arisen in the setting of managed care: the question of the physician's liability when, against his better judgment, but acting within the standards of the medical community, he takes a course of action directed by the third-party payer that, in the event, adversely affects the patient.

> The stakes, the risks at issue, are much higher when a prospective cost containment review process is utilized than when a retrospective review process is used.
>
> A mistaken conclusion about medical necessity following retrospective review will result in a wrongful withholding of payment. An erroneous decision in a prospective review process, on the other hand, in practical consequences, results in the withholding of necessary care, potentially leading to a patient's permanent disability or death.[31]

The California Court of Appeals dealt with this issue in the landmark case of *Wickline v. California*.[32] The claimant, Mrs. Wickline, underwent surgery for a condition known as Leriche's Syndrome, which manifested itself in circulatory problems and recurring blood clots in the claimant's legs. Because of post-operative problems, her surgeon concluded that it was "medically necessary" to extend her hospital stay by eight days, a judgment in which her personal physician, as well as a physician who had assisted in the surgery, concurred. Because Wickline was covered under the State's

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[31] Jacqueline M. Saue, J.D., "Legal Issues Related to Case Management," 14 JCAH Quality Review Bulletin 239 (August, 1988).

[32] 228 Cal. Rptr. 661 (Ct.App. 1986). The Wickline case is discussed in the Saue article, cited in note 31.

Medi-Cal program, the on-site nurse called the Medi-Cal surgical consultant, a general surgeon, for approval. The Medi-Cal consultant, after speaking with the on-site nurse, but not with Wickline's physicians, agreed to a four-day extension.

Subsequent to her discharge, Wickline's condition worsened, ultimately necessitating the amputation of one of her legs. She sued Medi-Cal, but not her physicians. Her surgeon testified at the trial that, although all of the physicians had acceded to the Medi-Cal consultant's decision, he believed "to a reasonable medical certainty that the claimant would not have suffered the loss of her leg if she had remained in the hospital for the eight days requested."

The California Court of Appeals, reversing a lower court decision in favor of Wickline, held that the earlier discharge, in which the claimant's physicians had concurred (albeit reluctantly) was within accepted medical standards. It did observe, however, that (1) a third-party payer would be held liable for erroneous medical decisions resulting from its actions, and (2) a physician could not shift legal responsibility for his patient's welfare to a third-party payer by complying with a cost-containment program.

This area of the law continues to evolve. No clear trend has emerged.

The Role of State Statutes

For at least a decade, culminating in the mid-1980's, the frequency of malpractice claims, as well as the size of malpractice awards, both vastly increased. Since then, their frequency has somewhat declined.[33] But, as one author has pointed out:

> Assembling data to analyze empirically recent trends in medical malpractice cases can be difficult. For the most part, malpractice data are not systematically collected and analyzed, making it difficult to estimate the scope of the malpractice problem.[34]

In general, defendants appear to win most of the cases that go to trial, although this is more true in rural than in urban areas.[35]

In response to what has widely been perceived as a crisis for the health care system,[36] States have enacted an increasing number of statutes to limit the amount of recovery for medical malpractice, or require malpractice claims to be submitted to a pretrial panel. These statutes have spawned a raft of cases

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[33] Jacobson, "Medical Malpractice and the Tort System," 262 JAMA 3320-3327 (1989).

[34] Jacobson, op. cit. note 33.

[35] Jacobson, op. cit. note 33. The author writes: "A recent [1989] survey in three largely rural states reported that the defense prevailed in 81% of the litigated cases. Data from the 1987 American College of Obstetricians and Gynecologists survey indicate that defendants won 68% of all claims adjudicated by arbitration or jury verdict, although this was down from 81% reported in the 1985 American College of Obstetricians and Gynecologists survey. At least in urban areas, however, plaintiffs may be winning a higher percentage of medical malpractice verdicts than 20 years ago. Peterson reports that plaintiffs' victories in medical malpractice cases increased during a 20 year period from 27% to 53% in San Francisco, California, and from 25% to 49% in Cook County." [Footnotes omitted]

[36] Nye, Gifford, Webb, and Dewar, "The Causes of the Medical Malpractice Crisis: An Analysis of Claims Data and Insurance Company Finances," 76 Geo. L.J. 1495, 1508 (April 1988).

dealing with their constitutional validity and the construction of specific statutory provisions.[37]

In addition to these statutes, some States have placed caps on non-economic damages, have required that a malpractice award be reduced by insurance or other benefits received by the claimant because of the injury, and have shortened the time period, after the injury, during which a claim must be filed.

So far, at least, no general doctrines seem to have emerged. Some holdings have found particular statutes to violate constitutional guaranties of equal protection; some have found otherwise.[38]

In one clear area of agreement, nevertheless, the courts have uniformly held that statutes limiting recoveries in malpractice actions apply only prospectively. That is, they do not apply to an injury that occurred prior to the statute's effective date, even though the claim based on the injury had not been resolved by that date.[39]

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[37] See Karnezis, op. cit. in note 28.

[38] The legal issue is whether the distinction between those who are damaged as a result of medical malpractice, whose recovery would be limited, and those who are damaged by other forms of negligence, whose recovery would not be limited, is arbitrary (i.e., does not have a fair and substantial relationship to the achievement of the legislature's objective). Compare Wright v. Central Du Page Hospital Association, 63 Ill. 2d 313 (1976) (striking down a statutory provision that imposed a $500,000 recovery limitation only on medical malpractice actions, as creating an arbitrary classification amounting to special legislation in violation of an equal protection provision of the Illinois Constitution), and Kranda v. Houser-Norborg Medical Corp, 419 N.E. 2d 1024 (1981) (statutory provisions that capped recovery amounts in medical malpractice cases found an unconstitutional denial of Kansas Constitution Bill of Rights sections regarding trial by jury and justice without delay), with Jones v. State Board of Medicine, 97 Idaho 859, 555 P. 2d 399 (1976) (upholding a statute against a claim of violation of due process). For an exhaustive listing of such cases, see Karnezis, op. cit. note 28.

[39] See, for example, Young v. Alberts 73 Ohio Ops.2d 32, 342 Ne.E. 2d 700 (1975), Simon v. St. Elizabeth Medical Center, 3 Ohio Ops. 3d 164, 355 N.E. 2d 903 (1976), and Allen v. Fisher, 118 Ariz. 95, 574 P.2d 1314 (1977).

The Effect of Malpractice Litigation on Health Care Costs

The general trend of judicial decisions in malpractice cases has been to drive up the costs of health care.

Since 1985, average professional liability premiums have increased at an average annual rate of 13.9% for all physicians, with an average nationwide professional liability premium in 1989 of $15,500.[40]

Professional liability insurance of all self-employed physicians represented 4.9 percent of total practice revenues in 1989, from a high of 9 percent for general surgeons, obstetricians, and gynecologists to a low of 2.1 percent for pathologists.[41] The average premium in that year was $15,500, from a high of $37,000 for obstetricians and gynecologists to a low of $5,500 for pathologists.[42]

But "the available evidence suggests that physicians have not been able to charge patients increased fees sufficient to offset fully their increased premium costs."[43] In consequence, one cannot translate the costs of professional liability insurance into patient charges.

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[40] Slora and Gonzalez, "Medical Professional Liability Claims and Premiums, 1985-1989," as it appears in AMA Center for Health Policy Research, *Socioeconomic Characteristics of Medical Practice 1990/1991*, p. 15 et. seq.

[41] Gillis and Willke, "Practice Cost Shares of Self-Employed Physicians," AMA Center for Health Policy Research, *Socioeconomic Characteristics of Medical Practice 1990/1991*, Table 2, p. 23.

[42] Slora and Gonzalez, "Medical Professional Liability Claims and Premiums, 1985-1989," AMA Center for Health Policy Research, *Socioeconomic Characteristics of Medical Practice 1990/1991.*

[43] Nye, op. cit. note 36, p. 1508.

Adverse Outcome as a Cost of Medical Care

Insurance premiums reflect malpractice awards, and as previously noted malpractice awards are commonly cited as causing a crisis in the provision of health care.[44] But any attempt to quantify the effect of malpractice awards on the costs of health care must appreciate that direct damages do not necessarily increase the costs of health care; it may only redistribute them.

If one eliminates those portions of a malpractice award—pain and suffering, loss of consortium, and so on—that do not compensate for economic loss, the remaining portion of the award—by far the larger portion, on average, in cases involving permanent injury affecting earnings—is generated, when fairly and properly calculated, by the malpractice itself.

For example, assume a case in which an individual 40 years of age, with average earnings of $25,000 a year, is totally disabled because of malpractice in the course of a routine surgical procedure. If one disregards any other fiscal consequence to the individual, and further assumes that he has a remaining life expectancy of 30 years, the malpractice has cost him a commuted amount, at the current interest rate of long-term government securities, of nearly $270,000. This $270,000 is a cost of health care that, in the absence of tort liability, would have to be borne by the individual, his family, or the welfare system.

Beyond the expense to an individual in obtaining health care, in other words, there is the expense that the care may inflict on him. For this reason, it is

[44] For example, Eliot Martin Blake, in "Rumors of Crisis: Considering the Insurance Crisis and Tort Reform in an Information Vacuum," 37 Emory L.J. 401 (Spring 1988), claims, "In Florida, nearly one-third of obstetricians have stopped delivering babies, citing the expense of medical liability coverage," p. 402.

not wholly accurate to speak as though the entire consequence of the tort system on the provision of medical care is to increase its cost. That is true only if the focus is exclusively on the front end: the price of buying it. If the focus is broadened to include all of the costs of health care, it is apparent that much of the effect of a malpractice judgment is to spread, not necessarily increase, some of those costs.

This has conceptual implications for the policy maker. If, for example, a policy that favors caps on malpractice awards does not distinguish between economic and non-economic losses, it will confuse different legal bases for malpractice awards, and therefore different policy concerns.

Monetary awards for consequential damages—pain and suffering, punitive damages, loss of consortium, and the like—are not to compensate the claimant for economic losses. Necessarily, then, their size is arbitrary. It is said, not wholly in jest, that the award for pain and suffering is to provide a fee for plaintiff's counsel.

In the absence of a rationale for converting non-economic injury into its dollar equivalent, a proposal to limit their size becomes one of equal protection (i.e., whether the social importance of constraining increases in health care costs establishes a reasonable basis for imposing on victims of malpractice a limitation in the amount of consequential damages that they may recover that is not imposed on other litigants).[45]

Direct damages, however, are to compensate for actual loss. Therefore, a decision to cap economic damages is fundamentally a decision that the individual purchaser of health care services should bear some part of the

[45] See the discussion, and cases cited, in note 38.

economic risk associated with their imperfect delivery. It is a decision, in other words, against spreading the purchaser's real economic loss to the health care system as a whole through increased liability premiums for health care providers. This is a far harder policy to defend than one that seeks only to limit consequential damages.

The Question of "Excess" Cost

If the legal distinction between direct and consequential damages, as described above, is accepted as the basis for a policy distinction that would characterize the latter as the "excess" cost of the tort system, one question for the policy maker is what proportion of a malpractice award is, in this sense, "excess?" Once one moves beyond the awards in decided cases, there is no ready answer. The problem is one of evaluating the excess cost of the multitude of settlements entered into to avoid litigation.[46] As the HHS Task Force on Medical Liability and Malpractice pointed out:

> Malpractice claims can be resolved prior to a judicial determination by agreement of the parties. These settlements between patient claimants and health care providers are influenced by the parties' assessment of what a potential judicial determination would be. But factors other than the potential judicial determination—such as the cost of protracted litigation compared to an early settlement—also influence such settlements, in which the interests of the insurer play a significant role.

[46] As a rule of thumb in the average tort case involving physical injury, say an automobile accident not resulting in long-term disability or permanent injury, consequential damages are usually agreed upon in an amount equal to between three and four times the costs of medical care. Awards in malpractice cases are more problematical.

> As a result settlements cannot be equated directly with a determination of malpractice.[47]

Nor is there a simple way of either, on the one hand, estimating the economic injuries caused by treatment that would have been held to be malpractice except that no claim was ever filed; or, on the other hand, adjusting for unreasonable malpractice awards to individuals undergoing medical or surgical procedures the successful outcome of which, given the limitations of the art, was necessarily problematical.[48]

The Cost of "Defensive" Medicine

Finally, in estimating the costs of judicial doctrines in professional liability cases, there is the cost of "defensive medicine." One usually thinks of defensive medicine as a body of medical practice undertaken by health care providers solely to avoid tort liability. The problem is described by Clark C. Havighurst in these terms:

> [T]he legal system now constitutes a significant . . . form of economic regulation . . . providers of care must measure up to the law's standards and do not have the option of agreeing with their patients on any others.

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[47] Task Force Report, op. cit. note 27, at p. 7.

[48] Jacobson points out: "When evaluating jury behavior in medical malpractice cases, two interrelated issues should be considered. The absence of definitive research on appropriate outcomes from medical procedures (that is, the distribution of outcomes that can reasonably be expected from medical intervention) makes it difficult to establish whether the outcome in any given situation results from inappropriate care (negligence) or bad luck. Confounding this problem is the equally difficult issue, particularly in birth-injury cases, of attributing an adverse outcome to a particular cause. Scientific notions of causation (established through probabilistic reasoning) are very different from the legal determination of proximate cause and can be difficult to reconcile in an individual case." [Jacobson, op. cit. note 33, footnotes omitted]

> Because deviations from professional standards are so effectively precluded by law and circumstance, Americans are forced either to purchase first-class, state-of-the-art, Cadillac-style medical care or to go without coverage altogether.
>
> Judicial overregulation of health care is most apparent, of course, in medical malpractice litigation. In malpractice cases, the legal system regularly gives professional norms and standards—even ill-defined and poorly conceived ones—the force of public regulations. . . . This vagueness of professional standards in turn induces the widespread practice of "defensive medicine," as physicians, in an effort to avoid entanglement with a seemingly arbitrary legal system, err consistently on the side of spending too much rather than too little.[49]

This is not to suggest that the physician who practices defensive medicine necessarily employs tests and procedures that are medically unnecessary. If they were, it is unlikely that the failure to undertake them would run a serious legal risk.

It would be instructive to put to a representative sample of physicians a survey question: "What actions do you routinely take in your practice that you consider medically unnecessary, but needed, nevertheless, to guard against the risk of a malpractice action?" One can be fairly confident that there will be few actions described that some responsible physicians would not consider prudent and proper in the circumstances.

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[49] Havighurst, "Why Preserve Private Health Care Financing?" A paper delivered for a seminar of the American Enterprise Institute for Public Policy Research on "American Health Policy: Critical Issues for Reform," October 3-4, 1991, Washington, DC, on pages 20-21.

It is probably more accurate to describe defensive medicine as professional conduct intended to guard against relatively remote medical contingencies. In other words, it is what Havighurst describes as "first-class, state-of-the-art, Cadillac-style medical care," drawn from the profession's own highest norms. It errs on the side of care that is the most, rather than the least, costly.

It must be remembered that no test or procedure has a marginal utility of zero to a patient who benefits from it, even if it is administered by a physician solely to guard against a malpractice claim. A patient may well accept the physician's judgment, based on risk/benefit analysis, that the advantages of the test or procedure do not outweigh its risks. But, particularly if costs are to be paid by a third-party payer, the patient is less ready to accept a judgment based on cost/benefit analysis: the benefits likely to accrue to the patient do not justify the cost of the test to the health care system.

To conclude, then, that defensive medicine imposes "unnecessary" costs on the system implies a policy judgment that some lower standard of care is desirable because it is cheaper. What standard? At one time, the courts applied a "locality rule," under which the standard of care was that of the defendant's practice area. Now, however, the standard appears to be nationwide.[50]

In short, to measure the costs of defensive medicine, one must adopt some baseline of less than first-class care; but there is no agreement among physicians, as far as the Council is aware, as to how to define such a standard.

[50] Jacobson, op. cit. note 33.

This being said, it remains true that the fear of malpractice encourages the use of technology that, whatever its occasional utility in the individual case, probably has a negative cost/benefit from a broader social perspective. For example:

> There is no doubt that many obstetricians have been encouraged to use EFM [electronic fetal monitoring] because of a fear of liability for not using the "customary procedure." The precise impact of malpractice concerns on the diffusion of EFM, however, has not been measured.[51]

The irony is:

> . . . this fear of liability may not be well grounded. Careful reading of the relevant legal literature indicates that failure to use EFM should not result in liability, whereas using EFM in a routine labor and delivery may result in malpractice allegations.[52]

Physicians are not lawyers, and not necessarily well versed in the nuances of court decisions. In consequence, some portion of the practice of defensive medicine—that portion that may, in fact, involve unnecessary tests or procedures—responds to a physician's misapprehension of what the courts have held. This aspect of defensive medicine increases the costs of medical care, but increases them unnecessarily; but perhaps most importantly, defensive medicine increases costs in another way: its practice operates to raise the standard of care.

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[51] Stephen B. Thacker, M.D., M.Sc., "The Impact of Technology Assessment and Medical Malpractice on the Diffusion of Medical Technologies: The Case of Electronic Fetal Monitoring," Institute of Medicine, *Medical Professional Liability and the Delivery of Obstetrical Care (1989)*, at page 21.

[52] Thacker, loc. cit.

> To the extent that physicians order additional tests as protection against subsequent liability, the added tests become part of the changing standard of care.[53]

As the standard of care increases, the cost of medical care increases. From a policy standpoint, not everyone would agree that increasing the standard of care is an undesirable result.

[53] Jacobson, op. cit. note 33.

Legal Doctrines

State law, not Federal law, governs the liability of manufacturers to individuals who allege injury from prescription drugs and medical devices claimed to be defective. The litigation, itself, is conducted primarily in State courts, except when it is between citizens of different States or involves parties who are citizens of a foreign government. In those cases, it may be tried by a Federal court; but the court will apply the law of the State in which the injury occurred.[54]

Under State law, the usual rule is that a manufacturer is strictly liable for the sale of a product in a defective condition that makes it unreasonably dangerous to the user.[55] What this means, essentially, is that the injured plaintiff need not show that the manufacturer was negligent. Thus, for example, the manufacturer of an oral polio vaccine was held strictly liable for the injury to adults who contracted polio after immunization with it, notwithstanding that no negligence was shown in the vaccine's manufacture.[56]

What the plaintiff must show, of course, is some nexus between his injury and the product, and the absence of any warning of the danger. This is a

[54] Even an individual injured by a product that is sold in violation of the Federal Food, Drug, and Cosmetic Act does not thereby acquire a federal cause of action. Merrell Dow Pharmaceuticals, Inc. v. Thompson, et al., 478 U.S. 804 (1986).

[55] See Restatement of Torts, 402A, and cases collected at 66 A.L.R. 4th 83 (1991).

[56] Grinnell v. Charles Pfizer & Co., 274 Cal. App. 2d 424 (1969).

relatively straightforward matter if the injury is caused, as in *Webb v. Kern,*[57] by the explosion of a beer keg. It is far more difficult, as the many unsuccessful lawsuits over Merrell Dow's Bendectin attest, when the product is a drug.[58] Nevertheless, the law is rarely at issue in these cases—only the facts.

Liability Trends

The pharmaceutical and health product industries are unusual in that from time to time a single widely disseminated product will stimulate a virtual blizzard of litigation. The Dalkon Shield, an intrauterine contraceptive device manufactured by the A.H. Robins Company, became the subject of more than 5,000 lawsuits and almost 200,000 successful claims, forcing the company to file for bankruptcy.[59]

> One of the prominent characteristics of this industry is that large companies market certain drugs or pharmaceutical preparations that are widely used, sometimes by millions of consumers. If only a small percentage of these consumers experience injuries that they believe, rightly or wrongly, to be associated with the use of the product, an "epidemic" of lawsuits can rapidly ensue.[60]

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[57] 422 Pa. 424 (1966).

[58] "Approximately 800 Bendectin suits were consolidated in the Southern District of Ohio and handled as a class action. A trial was held in February of 1985, and the company won at the district court level on the grounds that a causal relationship between Bendectin and the injuries claimed by plaintiffs had not been demonstrated." Dungworth, "Product Liability and the Business Sector: Litigation Trends in Federal Courts," The Institute for Civil Justice, Rand (1988), p. 41.

[59] Dungworth, op. cit. note 58, p. viii, n. 2.

[60] Dungworth, op. cit. note 58, p. 41.

This happened in the case of Bendectin, a morning-sickness drug administered to pregnant women. More than 33 million women used the drug. Some users came to believe that the drug caused birth defects, and the manufacturer, Merrell Dow Pharmaceuticals, Inc., removed it from the market. Nevertheless, of the more than 1,150 cases against Merrell Dow adjudicated by trial in the Federal courts by 1988, the company prevailed in all but four.[61]

If these major manufacturer/single-product "epidemic" cases are excluded from consideration, the filing trend for other defendants did, nevertheless, exhibit a steady growth throughout the 1980's that far exceeded the rate of increase for other product liability litigation.[62]

There is some suggestion that the frequency of health product litigation has gone down in recent years, but there has been a corresponding escalation in the severity of claims. The reason for this trend is not known.[63]

Costs of Litigation

There is little published data on the costs of litigation over injuries claimed to have resulted from drugs or medical devices. The Institute for Civil Justice of the Rand Corporation is currently studying question of product liability costs, but the work is not yet complete.[64]

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[61] Dungworth, op. cit. note 58, p. viii, n. 3.

[62] Dungworth, op. cit. note 58, p. 42. Dungworth does not examine state court litigation because figures are not available.

[63] Personal communication with Mr. Jaxon White, president of the Medmarc Insurance Company.

[64] Conversation with Dr. Kevin F. McCarthy, Director, The Institute for Civil Justice, Rand Corportion. The Council wishes to express its appreciation to Dr. McCarthy for the material that he provided on this subject, and which forms much of the basis for the text of this section of the report.

Mr. Jaxon White, President of Medmarc Insurance Company, which insures 500 medical device manufacturers, estimates the costs of medical device product liability to be, on average, about four percent of the sale price of every medical device: about $11 million a year for the companies that Medmarc insures.[65] This compares to a 1988 estimate for manufacturing firms in general of less than one percent.[66]

Direct Costs to the Health Care System

Whatever the costs of litigation to prescription drug and medical device manufacturers, there is no way to translate those costs into some ascertainable charge on the health care system. Certainly manufacturers must know their costs if they are to price the products for profit. But the costs to manufacturers of product liability insurance is small in relation to the probable profit to be earned from a new product.

If the product is useful and sold within its patent term, one may expect the manufacturer to seek and get a price that returns to it the cost of developing the product and a healthy profit besides. If the product must compete with cheap generic versions, one may expect the price to be fairly competitive. In short, the market will set the price, with the consequence that no portion can be identified as directly attributable to the cost of liability insurance.

[65] Personal communication on November 6, 1991.

[66] Reuter, "The Economic Consequences of Expanded Corporate Liability: An Exploratory Study," The Institute for Civil Justice, Rand Corporation (November 1988), page v.

But, as explained in the next section, if one limits one's concern to the direct costs of product liability litigation, one will overlook the most serious effects of this litigation on the cost of health care.

Hidden Costs to the Health Care System

The major costs of product litigation are hidden costs: the effect of litigation on the conduct of the firms involved: " . . . each liability should be seen to represent a set of rules that provide incentives for firms and potentially shape their behavior in many dimensions."[67]

Peter Reuter, in a Rand Note for the Institute for Civil Justice, explains the issue through a simple matrix:[68]

DECISION	OUTCOME	
	Safe	Unsafe
Market	P_{11}	P_{12}
Not Market	P_{21}	P_{22}

The diagonal entries, P_{11} and P_{22} represent the socially desirable outcomes (i.e., a manufacturer's decision to market a safe product [P_{11}] and not market

[67] Reuter, "The Economic Consequences of Expanded Corporate Liability: An Exploratory Study," The Institute for Civil Justice, Rand Corporation (November 1988).

[68] Reuter, op. cit. note 67, p. 7.

an unsafe one [P_{22}]).[69] A manufacturer's decision to market an unsafe product (P_{12}), what Reuter calls a "Type I error," may lead to injury and litigation, a relatively visible cost of health care.[70] The hidden cost to the system is the Type II error: the decision to withhold a product that is fundamentally safe and useful. One might argue that Merrell Dow's withdrawal of Bendectin was a Type II error. This cost may be social and not financial, or it may be both. In either case, it is hidden, because it is difficult to find out about products not brought to market because of fear of liability.

> Product marketing decisions are made under uncertainty. Even after extensive product testing has been conducted, a manufacturer cannot be certain that a product will not cause injury and engender suits once it is in the hands of distributors and consumers. Thus, under any conceivable legal regime, producers as a group may make some errors of both types. Ultimately, a firm will make its decision after considering the payoffs associated with each potential decision and outcome . . . the higher the negative payoff associated with the marketing of an unsafe product, the greater the probability of safety the firm will require before marketing a product.[71]

Expanded liability—the move from liability for negligence to a standard of strict liability—generates at least two responses. First, a firm may incur a greater expense to test its products; second, a firm may also, or alternatively, alter its marketing strategy. If, for example, a medical device with expected

[69] Of course, in the prescription drug and medical device field, probably no product is entirely safe. The matrix must be understood, in the context of new prescription drugs and Class III medical devices, as referring to products for which the Food and Drug Administration would grant premarket approval.

[70] *Ibid*, note 68.

[71] Reuter, op. cit. note 67, p. 8.

sales of 200,000 items would have been marketed unless the probability of fatalities was more than 1 in 10,000, a stricter liability standard may cause the manufacturer to withhold the device unless the probability is less than 1 in 100,000. In this last case, the probability of a Type II error—overestimation of the risk—increases.

> The objective of expanded liability is to reduce one kind of error, generally what we have called the Type I error, e.g., fewer unsafe products should be marketed. That such a reduction is not costless is well recognized. What tends to be less well recognized is that in an uncertain world, reduction of the frequency of Type I errors may well be associated with increasing the frequency of Type II errors.[72]

A survey of pharmaceutical manufacturers determined that "the inhibiting effect of expanded product liability is difficult to quantify because it permeates a firm's decisionmaking process," even down to the bench chemist who does not pursue his curiosity about, say, a pregnancy-related drug, " . . . because he knows that the firm's senior management is unlikely to fund later and more costly stages of the development process for such a high-hazard product."[73]

The most dramatic illustration of the effect of the strict liability standard on drug manufacturers is the history of the marketing of the swine flu vaccine in 1976. The liability insurers of all four manufacturers of the vaccine refused to accept the risk of claims by individuals alleging injury from vaccination. As a result, the manufacturers refused to proceed.

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[72] Reuter, op. cit. note 67, p. 9.
[73] Reuter, op. cit. note 67, p. 26.

> It was not the fear of liability for manufacturer negligence that concerned the insurance companies; instead, it was the risk of strict products liability and the anticipated cost of defending the many meritless suits that the companies believed would be filed.[74]

In order to get the swine flu immunization program underway, it was necessary to enact legislation substituting the government as the party defendant.[75]

The National Vaccine Injury Compensation Program[76] substitutes the Federal government for the vaccine manufacturer in certain cases of injury, above $1,000 dollars, resulting from vaccines for childhood diseases, i.e., DTP, measles, mumps, rubella, and polio. In proposing the enactment of the current version of this program, the Secretary of Health and Human Services, Otis Bowen, wrote to the Speaker of the House and the President of the Senate:

> The draft bill would address concerns expressed by the President last November when he signed the Omnibus Health Bill that contained, as Title III, the National Childhood Vaccine Injury Act. At that time, he noted:
>
> > The Administration has been greatly concerned for some time that unpredictable tort liability has caused many vaccine manufacturers to abandon production of childhood vaccines . . . Title III addresses only the worthy purpose of

[74] Hunt v. U.S., 636 F. 2d 580 (1980), citing the remarks of Rep. Rogers, 122 Cong. Rec. 26, 796, 26, 799-800, 26, 808-09 (1976).

[75] See the National Swine Flu Immunization Program of 1976, P.L. 94-38, 90 Stat. 1113 (1976).

[76] Sections 2110 et. seq. of the Public Health Service Act, 42 U.S.C. 300aa-10 et. seq.

compensating persons who have been injured by childhood vaccinations.[77]

In short, the threat of tort liability was so great that the government was compelled to assume its risk in order to induce vaccine manufacturers to continue to produce and sell the vaccine.

[77] 133 Cong. Rec. § 16870, Tuesday, December 1, 1987.

TERMINATION OF CARE LITIGATION

State Judicial Doctrines

Origins of the Right to Refuse Medical Treatment

The right of an individual to refuse medical care—although not in the context of life-threatening illness—was asserted and judicially upheld as early as the beginning of this century.[78] Its existence flowed naturally from a legal concept as old as the English common law: the right of an individual to recover damages for a trespass against—an unconsented touching of—his person.

In recent times, the right of a competent individual to refuse medical treatment has been viewed as an aspect of the common law doctrine that allows medical treatment to be withheld with the informed consent of the patient.[79]

> [W]ith the advance of medical technology capable of sustaining life well past the point where natural forces would have brought certain

[78] Pratt v. Davis, 224 Ill. 300, 79 N.E. 562 (1906) (Damages awarded against a physician who performed an unauthorized surgical procedure without the consent of the patient or her representative).

[79] See, e.g., the Cardozo opinion in Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914), "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."

death in earlier times, cases involving the right to refuse life-sustaining treatment have burgeoned.[80]

Although the Supreme Court, in *Cruzan v. Missouri Department of Health*,[81] has now addressed this question from the standpoint of constitutional guaranties of due process of law, the critical doctrines remain State doctrines.

Competing Concerns: The Saikewicz Case

Belchertown v. Saikewicz,[82] a case decided by the Supreme Judicial Court of Massachusetts, has been the lodestone for other jurisdictions. Joseph Saikewicz, a profoundly retarded 67-year-old resident of the Belchertown State School, was found to be afflicted with acute myeloblastic monocytic leukemia, a disease that was invariably fatal. The treatment available at the time was limited to a form of chemotherapy that caused considerable suffering (and in some cases death), was ineffective in most cases for persons of Saikewicz's age, and at best could be expected to cause a remission of between two and 13 months. A decision to allow the disease to run its natural course would not cause the patient pain, and would result in a death, probably without discomfort, within several months. Saikewicz was incapable of giving informed consent to dispensing with medical treatment.

Upon the petition of the school, a probate judge appointed a guardian *ad litem*, who recommended "that not treating Mr. Saikewicz would be in his

[80] Cruzan v. Missouri Department of Health, 110 S. Ct. 2841 (1990).
[81] Op. cit. note 80.
[82] 373 Mass. 728, 370 N.E. 2d 417 (1977).

best interests." The probate court concurred in the recommendation, but reported the case for appellate review.

The Massachusetts Supreme Judicial Court took the view that the substantive rights of a competent and incompetent person were the same "in regard to the right to decline potentially life-prolonging treatment," and that there was a "general right in all persons to refuse medical treatment in appropriate circumstances."

The problem for the court was two-fold: (1) how is this right to be exercised if the patient is not competent to exercise it? and (2) what are "appropriate circumstances?"

Under general principles of law, the State stands in the relationship of *parens patriae* to incompetent individuals, i.e., it exercises a sovereign power of guardianship that requires it to act in the individual's "best interests." The court concluded that the best interests of an incompetent individual were not necessarily served by imposing a standard different from what would be imposed on a competent individual. It therefore resorted to what is known as the "substituted judgment" standard.[83] Instead of asking, "What would an objective observer consider to be in the patient's best interests?" it asks, "If this patient were competent, how would he choose?"

[83] The court quoted Professor Robertson of Wisconsin Law School, " . . . maintaining the integrity of the person means that we act toward him 'as we have reason to believe [he] would choose for [himself] if [he] were [capable] of reason and deciding rationally.' It does not provide a license to impute to him preferences he never had or to ignore previous preferences . . . If preferences are unknown, we must act with respect to the preferences a reasonable, competent person in the incompetent's situation would have." Robertson, "Organ Donations by Incompetents and the Substituted Judgment Doctrine," 76 Colum. L. Rev. 48, 63 (1976), quoting J. Rawls, *A Theory of Justice*, 209 (1971).

The court expressly disavowed any power to make a judgment based upon its assessment of a patient's "quality of life." Instead, against a choice to forego medical care, the court asserted four possible State interests:

- preserving life;
- protecting the interests of innocent third parties;
- preventing suicide; and
- maintaining the medical profession's ethical integrity.

It concluded, respecting the first point, that the State's interest in preserving life was not preeminent where the issue is not whether to preserve it but, rather, whether to prolong it briefly at great cost to the individual in suffering.

As to the second point, it could be disregarded in this case inasmuch as Saikewicz did not have minor children or dependents that would be deprived by his death.

On the question of suicide, the court took the view that the refusal of medical treatment does not necessarily constitute suicide because the patient did not "set the death producing agent in motion with the intent of causing his own death."

Finally, on the issue of the integrity of the medical profession, the court noted that the current state of medical ethics does not require the employment of extraordinary means of prolonging life when there is no hope for the recovery of the patient.

Accordingly, the court concurred in the judgment of the probate court and the guardian *ad litem*.

A principal limitation in applying *Saikewicz* to other cases is that the patient was terminal. The case necessarily left open what the result would have been if medical treatment could reasonably be expected to maintain an incompetent patient indefinitely.

The Non-Terminal Patient: The Quinlan Case

Just before *Saikewicz* was decided, this question had been answered by New Jersey: *In the Matter of Karen Quinlan.*[84] Quinlan was in a persistent vegetative state (i.e., irreversibly comatose); but, at the time of the decision, had been kept alive by a respirator for about a year. The court held that, using a substituted judgment standard, Quinlan's father could direct that the respirator be disconnected, over the ethical objection of Quinlan's physicians. It rested its decision on a "right of privacy" that the Supreme Court of the United States had most recently enunciated in *Roe v. Wade,*[85] which extended the right of privacy to encompass a woman's decision to terminate pregnancy.

Federal Constitutional Doctrine: The Cruzan Case

Then, in *Cruzan*, the Supreme Court was called upon to determine whether the State of Missouri could require clear and convincing evidence that the

[84] 70 N.J. 10, 355 A. 2d 647 (1976).
[85] 410 U.S. 113, 153 (1973).

withdrawal of artificial feeding and hydration equipment from a permanently comatose, but not terminal, patient was in accordance with the patient's wishes, expressed when she was cognizant.

The importance of *Cruzan,* which upheld State law, lies in its apparent recognition that, without regard to any asserted right of privacy, a *competent* person has a "liberty interest" under the Due Process Clause of the Fourteenth Amendment to the United States Constitution in refusing unwanted medical treatment, including nutrition and hydration, even if necessary to sustain life.

This implication is largely in accord with State cases interpreting State law.

Cost Implications

Over the last few decades, technological advances in prolonging life, the prevalence of third-party payers of medical care, and the aging of the population have invested the right to refuse medical care with new economic implications. To consider the age factor alone:

> Current Census Bureau middle-mortality series projections predict that the number of individuals over age 65 will increase to 52 million by the year 2020 and to 68 million by the year 2040. . . . [The projection] forecasts 6.7 million Americans age 85 and over by the year 2020 and 12.2 million by the year 2040.[86]

[86] Schneider and Guralnik, "The Aging of America: Impact on Health Care Costs," 263 *JAMA,* 2335-2340 (1990).

"As individuals enter the last decades of life, their needs for long-term care and the resultant costs increase exponentially."[87] This is no small matter. Among Americans in the 65 and over age group, it is estimated that 80 percent die in hospitals and nursing homes. Approximately 70 percent of those deaths occur after a decision is made to forego medical treatment to sustain life.[88]

A recent survey estimated that nationwide nearly 2,400 sitting trial court judges have heard at least 7,000 of these cases.[89]

The exercise of a right to refuse medical care—essentially, the exercise of a right to die—will thus bear increasingly on the national costs of health care. How much it will offset the rising expense of new technology that will undoubtedly continue to come on line to prolong life further is, to say the least, speculative.

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[87] Schneider, op. cit. note 86.

[88] Orentlicher, "The Right to Die After Cruzan," 264 *JAMA*, 2444-2446 (1990) (footnotes omitted).

[89] Hafemeister, Keilitz, and Banks, "State Courts and Decisions About Life-Sustaining Treatment," 324 New Eng. J. Med. 343 (Jan 31, 1991). The estimate was based on a survey questionnaire mailed to a random sample of state trial court judges. The authors wrote: "It can be argued that these represent relatively small numbers, considering that the American Hospital Association in its amicus curiae brief in the Cruzan case asserted that 70 percent of the 1.3 million people who die in American hospitals each year die after a decision to forego medical treatment has been made . . . However, cases about life-sustaining treatment do not exist in a vacuum. It is quite likely that a single case will reverberate throughout the local medical community, shaping the behavior of medical professionals even though their decisions were not on trial."

ANTITRUST LITIGATION

Health Care Providers and the Antitrust Laws

In recent years, apparently in response to administration deregulation initiatives intended to increase competition, the Justice Department and the Federal Trade Commission have moved under the antitrust laws, primarily section 7 of the Clayton Act, to prevent or reverse mergers of non-profit hospitals.[90]

The pertinent law is stated very broadly in language that prohibits actions where the effect may be substantially to "lessen competition." It is left to the Federal regulators, and to private lawsuits, to determine what that action is, guided by a long history of judicial rulings.

For most of that history, Federal regulators and the courts shared the view that hospitals were organizations that were fundamentally noncompetitive. There were two reasons for this view. Because they were non-profit, hospitals were thought not to engage in price competition. Then, too, the demand for health care was believed to be "independent of the price of services or the activities of normal consumers."[91]

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[90] Pertinent sections other than §7 of the Clayton Act, 15. U.S.C. 18 (which prohibits mergers and acquisitions having the effect of substantially lessening competition or creating a monopoly) are §1 of the Sherman Act, 15 U.S.C. 1, which prohibits concerted activity that restrains trade, §2 of the Sherman Act, which prohibits unlawful monopoly, and §5 of the Federal Trade Commission Act, which prohibits unfair trade practices.

[91] Hunter, "Defining the Relevant Market in Health Care Antitrust Litigation: Hospital Mergers," 75 Ky. L.J. 175 (1986).

Irrespective of any question of whether the health care market was a normal economic market, it was also not clear that the expansion or merger of local hospitals burdened interstate commerce, the jurisdictional basis for the antitrust laws.

As a result, neither the Justice Department nor the Federal Trade Commission sought to apply the antitrust laws to hospital mergers. Then, in 1976, the Supreme Court held that the relocation and expansion of a local hospital did come within the jurisdiction of the Sherman Act.[92]

Most recently, in *United States v. Rockford Memorial Corporation*,[93] the United States Court of Appeals for the Seventh Circuit announced, for the first time at the Federal appellate level, that section 7 of the Clayton Act, one of two provisions of law that prohibit mergers intended to lessen competition, applies to non-profit corporations.[94]

The Concept of Market Power

Under the doctrines that dominated the legal landscape in the 1960's, the courts did not need to find that there had, in fact, been collusion from which price increases resulted. If it found that the market share of the merged organization reached or exceeded some high percentage of the market, the

[92] Hospital Bldg. Co. v. Trustees of Rex Hospital, 425 U.S. 738 (1976).

[93] 898 F. 2d 1278 (7th Cir. 1990), cert. den. 111 S. Ct. 295.

[94] A curious feature of this case is that the government failed to make this argument, and therefore waived it. The court, in fact, held for the government under §1 of the Sherman Act. Nevertheless, the court's pronouncement that it would have found that the Clayton applied was quite significant, particularly inasmuch as the opinion was written by Judge Posner, who came to the bench from the Chicago Law School faculty, where he was considered an expert on antitrust law.

court presumed monopoly power, and therefore illegality.[95] At that point, the defendant assumed the burden of rebutting that presumption by showing that the normal inference to be drawn from a market share of that size was, in the circumstances, mistaken.[96]

As economic analysis has become a more sophisticated tool, those doctrines may have somewhat eroded.[97] Under section 7 of the Clayton Act, as well as under section 1 of the Sherman Act (which indisputably applies to nonprofit corporations), the standard for measuring the lawfulness of a merger is now the same:

> Applied to cases brought under section 7, [the principle of competition] requires the district court ([or the Federal Trade] Commission) to make a judgment whether the challenged acquisition is likely to hurt consumers, as by making it easier for the firms in the market to collude, expressly or tacitly, and thereby force price above or farther above the competitive level.[98]

The ultimate question remains one of market power, i.e., the ability of a seller profitably to restrict output and raise prices above competitive levels without losing a large part of its business, or to depress prices for a product below the competitive price.

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[95] United States v. Aluminum Co. of America, 148 F. 2d 416, 424 (2d Cir. 1945).

[96] U.S. v. Rockford Memorial Corporation, op. cit. note 93.

[97] Judge Posner observed, in Hospital Corporation of America v. FTC, 802 F. 2d 1381 (7th Cir. 1986): "The most important developments that cast doubt on the continued vitality of such cases as Brown Shoe and Von's [cases employing a market share concept] are found in other cases, where the Supreme Court, echoed by the lower court, has said repeatedly that the economic concept of competition, rather than any desire to preserve rivals as such, is the lodestar that shall guide the contemporary application of the antitrust laws, not excluding the Clayton Act."

[98] Hospital Corporation of America v. FTC, 807 F. 2d 1381, 1386 (7th Cir. 1986).

In determining market power, two factors are controlling: the relevant market—the output of the suppliers to which customers can turn—and the defendant's share of it. A high share suggests market power.

The Justice Department Guidelines

Antitrust actions are time-consuming and expensive.[99] Therefore, except perhaps for the largest and economically strongest health care providers, the primary concern of a provider that seeks to merge with (or acquire) another provider is not how a court would ultimately rule in an antitrust action brought against it by the government, but whether the government will bring the action in the first place.

If the provider is not concerned with calling attention to itself, and is prepared to accept delay, it can seek government approval in advance of the merger or acquisition.[100] Or it can attempt to predict government action by turning, instead, to the Department of Justice Merger Guidelines.[101]

The Relevant Market

In considering, under the Guidelines, whether a horizontal merger—the merger of firms in the same product and geographic market—creates market power:

[99] See Hospitals, "Battling the FTC Proves Costly, Frustrating," July 20, 1991, p. 68.

[100] The Justice Department will provide advance guidance under a Business Review Procedure, 28 CFR 50.6.

[101] 49 Fed. Reg. 26823 (June 29, 1984).

> . . . the Department will focus first on the post-merger concentration of the market and the increase in concentration caused by the merger. For mergers that result in low market concentration or a relatively slight increase in concentration, the Department will be able to determine without a detailed examination of other factors that the merger poses no significant threat to competition. In other cases, however, the Department will proceed to examine a variety of other factors relevant to that question.[102]

For this purpose, the relevant market is "the smallest group of products and geographic area that could be subjected to the exercise of market power."[103]

In a hospital merger case, this is first defined by the geographic area in which the hospital is located. The hospital-defendant will argue that its service area is large, i.e., that it contains other hospitals with which the defendant must compete. The government will maintain that the service area is small, i.e., it contains few other hospitals with which the defendant must compete. But the product market must also be considered. "What products are sufficiently close substitutes to compete effectively in each other's market?"[104] The traditional test of whether two products are in the same market has been what is called their "cross-elasticity," i.e., the extent to which slight increases or decreases in price cause customers to switch.[105]

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[102] *Guidelines*, §3.

[103] *Guidelines*, §1.

[104] Pitofsky, "New Definitions of Relevant Market and the Assault on Antitrust," 90 Colum. L. Rev. 1805 (November, 1990).

[105] Introduced by United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377 (1956). The case is described by Pitofsky, op. cit. note 104, as follows: "In United States v. E. I. du Pont de Nemours & Co., commonly referred to by commentators as Cellophane, du Pont was charged with monopolizing the manufacture and sale of cellophane in violation of §2 of the Sherman Act. The Government argued that cellophane was the relevant product market, and that du Pont accounted for a 75% market share, with

(continued...)

The hospital will contend that the relevant product market is elastic, i.e., that it includes alternative services from other vendors that will serve the same purpose, and which are readily available to a potential patient who finds the price of a service offered by defendant to be uncompetitive. The government will maintain the contrary, i.e., that the alternative services will not serve the same purpose (e.g., if a patient needs a mastectomy, the availability of cataract surgery at an ambulatory care center in the service area is irrelevant), or that they are not readily available.

Calculating Market Shares

The Department of Justice uses the Herfindahl-Hirschman Index ("HHI") of market concentration to calculate the distribution of market shares, and therefore market power.[106] It is calculated by summing the squares of the individual market shares of all of the firms that the Departments finds to be included in the relevant market.

Assume, for example, a market consisting of 18 firms, one with a market share of 15 percent, and the remaining firms with a market share of 5 percent each. The market has an HHI of 650 ($15^2+5^2*17=650$). If the firm with the

[105] (...continued)
Sylvania, du Pont's sole competitor, accounting for the remainder. Du Pont countered that a proper relevant market was all flexible wrapping materials, including wax paper, glassine, pliofilm, and saran wrap, and that du Pont accounted for less than a 20% market share. Although there were findings that cellophane had significant differences from other flexible packaging materials, cost two to three times as much per surface measure as its chief competitors, and was the only flexible packaging material suitable to the needs of certain users (particularly cigarette manufacturers), the Court nevertheless concluded that the proper market included all flexible packaging materials.

"The Court's reasoning turned on the concept of 'cross-elasticity of demand.' It found that a slight increase or decrease in the price of cellophane caused a "considerable number of customers of other flexible wrappings to switch," demonstrating that the products competed in the same market. [footnotes omitted]"

[106] *Guidelines*, §3.1.

15 percent share now acquired six of its competitors, the after-merger HHI would be 2,300 (2,025 for the merging firms plus 25 each for the remaining 11 firms). The merger would therefore increase industry concentration by 1,650.

Roughly speaking, the Department considers a market unconcentrated if it has an HHI below 1000, moderately concentrated if it has an HHI between 1000 and 1800, and highly concentrated if it has an HHI above 1800.[107] Therefore, in the example, the acquisition, by changing an unconcentrated market into a concentrated one, invites an antitrust action.

The issue is not quite as simple as this, of course. For one thing, if there are no barriers to the entry of competition into a market, the Justice Department is unlikely to challenge the merger that (temporarily) concentrates it.[108] But in the health care provider field, barriers to entry are always very high.

In addition, the Department will bring many other factors to bear, among them the efficiency-enhancing potential of a merger that can increase the competitiveness of the new entity and therefore lower prices to consumers. This is a significant matter for hospitals that seek to merge, because their usual position, vis-a-vis the Justice Department and the Federal Trade Commission, is that the merger was not undertaken to reduce competition, but to reduce needless and expensive duplication of facilities, and therefore lower costs.

[107] *Guidelines*, §3.1.
[108] *Guidelines*, §3.3.

Significance for the Hospital Market[109]

Under the Justice Department Guidelines, the merger of two hospitals in a hospital market in which there are fewer than six hospitals—84 percent of communities with more than one hospital—will cause the merger to risk triggering an antitrust action. To date, the Justice Department and the Federal Trade Commission have focused on mergers in communities with fewer than four hospitals.

This creates a substantial problem for hospitals because Federal and State health care authorities have long encouraged hospitals to consolidate their resources in order to avoid wasteful duplication of services and facilities. In response, there is a growing trend among hospitals toward closure and consolidation. Annual survey data from the American Hospital Association, as reported and analyzed by a recent study, show that:

> . . . closures increased steadily between 1982, when only 23 hospitals ceased operation, and 1988, when a record number of 81 hospitals closed. Moreover, between 1982 and 1986, 79 hospital mergers occurred, 50 of which took place between 1984 and 1986. Recent estimates predict that by the year 2000 approximately 20% of the current acute care bed capacity will be closed.[110]

The reason for this trend is traceable to the decline, particularly over the last six years, in the utilization of inpatient hospital services.

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[109] The material under this heading is derived from a study by Robert W. McCann and William G. Kopit, "The Government's Hospital Merger Policy" (Jan. 1990).

[110] McCann and Kopit, op. cit. note 109, p. 8.

> Inpatient admissions fell 0.5% in 1983, 4.0% in 1984, 4.6% in 1985, 2.1% in 1986, 0.6% in 1987, and 0.7% in 1988. In total, over 4 million fewer people were admitted to hospitals in 1988 than in 1982. Concurrent with these reductions in admissions, inpatient lengths of stay have declined. The net result of these trends is that fewer patients are staying fewer days than in the first part of [the] decade.
>
> The trend has led to a steady decline in hospital revenue margins. Since 1984, total net revenue margins have declined 24%, and net patient revenue margins have declined 95% in the same period. In 1987, the average hospital earned just one dollar of surplus on each $1,000 of patient revenue. In 1988, aggregate patient revenue margins fell to zero.[111]

Nevertheless, the antitrust laws raise a significant barrier to most hospital mergers, even if undertaken solely to reduce costs in the face of declining revenues.

Mergers and the Cost of Health Care

The preceding discussion attempts to sketch, in broad and simplified outline, the major antitrust considerations that bear on mergers of health care providers. In reality, antitrust law is extraordinarily complex, rife with indecipherable economic jargon and judicial holdings that are hopelessly in conflict, and producing outcomes often hard to predict. Moreover, a modern revolution in the way hospitals conduct their business has added to the difficulty.

[111] McCann and Kopit, op. cit. note 109.

As one commentator observed:

> The health care system in the United States has undergone numerous changes in the past decade, with hospitals in particular leading the way. This $136 billion-a-year industry has experienced changes in the manner of receiving payments that have caused decreased utilization of inpatient services. As a result, hospitals have altered the way they conduct business. They have become more competitive and now can be compared to the many other profit-oriented businesses from which they are borrowing effective managerial and marketing techniques. Through strategic planning, hospitals are diversifying into related areas to establish a broader revenue base and a larger profit margin. Institutions failing to implement these changes likely will be purchased or cease to operate.[112]

These changes make the influence of antitrust decisions on health care costs problematical. As even a cursory reading of the major decisions quickly makes plain, the courts and the Federal Trade Commission are not mindlessly extending to health care providers, as targets of opportunity, antitrust laws intended by Congress to accomplish different purposes.

When the Clayton Act inhibits health care providers from merging, or agreeing among themselves to specialize in selected procedures, savings that would have been gained from a more efficient operation are presumably lost. The consumer or third-party payer is therefore deprived of so much of those savings as the provider would have passed along.[113]

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[112] Hunter, op. cit. note 91.

[113] McCann and Kopit, op. cit. note 109, cite these studies indicating that hospital prices are lower in more concentrated markets and higher in less concentrated markets: Robinson and Luft, "Competition

(continued...)

But the controlling question is whether, in the alternative situation, the provider would have offset—or more than offset—this hypothetical reduction in charges stemming from its more efficient operation against increases in charges that the provider's control of a monopolistic market would have empowered it to impose.

To answer this question in the negative is to assume that either health care providers are wholly immune from market forces (in which case there is no point in seeking to preserve a competitive market), or there are constraints, outside of market forces, that would act effectively to discourage providers from increasing their charges, regardless of whether monopolistic control of the market gives them the opportunity to do so.

It is probably true that price competition in the health care field is, and always will be, substantially muted.[114] It is also true that, irrespective of market considerations, the Federal government and the States are attempting to curb increases in provider reimbursement rates with increasing vigor.

> The Medicare prospective payment system, which has enormous significance to virtually every hospital, is far less a price-competitive model than simply a substituted form of regulation. Certainly, there is no pretense of market pricing in the PPS system. Thus, for most

[113] (...continued)
and the Cost of Hospital Care, 1972 to 1982," 257 *JAMA* 3241 (1987); Robinson and Luft, "Competition, Regulation, and Hospital Costs, 1982 to 1986," 260 *JAMA* 2676 (1988); and Melnick and Zwanziger, "Hospital Behavior Under Competition and Cost-Containment Policies: The California Experience, 1980 to 1985," 260 *JAMA* 2660 (1988).

[114] Donald Bray, president of the 709-bed University Hospital in Augusta, Georgia, is quoted as follows: "The hospital field doesn't have the same competitive pressures as other markets because only one-third of patients are affected by price competition." Hospitals, op. cit. note 99.

hospitals, almost half of their revenues come from governmental payers which set "prices" outside of any market mechanism.[115]

But it is equally true that health care providers often can and do respond productively under the impetus of a competitive market.

[115] McCann and Kopit, op. cit. note 109, p. 11.

CONCLUSION

This report began as an attempt to address the question, "What are the effects of private litigation on the costs of health care?" It ends with an appreciation that the answer depends upon what is meant by "the costs of health care."

If, somewhat artificially, one were to postulate an average base price for a particular service—the amount that the average health care provider currently charges for it—improving (or reducing) the quality of the service or unrelated inflationary (or deflationary) factors might alter this base price. Increasing the availability of the service would not, necessarily, alter its base price. If, however, the base price remained unchanged and other aspects of the health care system were stable, increasing the availability of a service necessarily increases the cost of the health care system as a share of the GNP.

Coverage decisions, which tend to increase the availability of a service, are of this last kind. They push up the costs of health insurance. But the increased premium pays for a real economic good: broader coverage. Therefore, one may expect that coverage decisions will be relatively neutral in their effect on the base price of services, except insofar as an increased demand may raise prices, and increased supply to meet that demand may lower them.

The other side of this picture is that coverage decisions, at least in theory, reduce the availability of health insurance. That is because, at some point, premium increases instituted in response to court-mandated coverage extensions will make the insurance less affordable. These increases exert a downward pressure on the cost of the health care system, because, without

health insurance, individuals cannot (or can no longer) utilize some health care services.

Malpractice decisions raise the premiums charged for professional liability insurance. They therefore increase the base price of services by an amount that depends upon the ability of the provider to pass the premium increases along to the consumer.

In this respect, however, malpractice awards must be divided into two parts. One portion, which compensates for economic losses, relieves an individual of costs that health care has inflicted upon him, and spreads those costs to the health care pricing structure generally. To some degree, this increases the base price of health care services. It does not increase the costs of the health care system; it merely moves some costs to the front end, where they can be accommodated in the pricing of services.

The second portion, which "compensates" for noneconomic ("consequential") damages—pain and suffering, loss of consortium, etc.—or is intended to be punitive, increases the base price of health care services. But it also increases the costs of the health care system, because consequential damages do not represent real costs inflicted on anyone by health care services.

This is not to discount suggestions of a malpractice crisis. Malpractice awards, by driving up professional liability insurance premiums, drive up the price of health care and reduce its availability. But policy makers must appreciate, in addressing the problem of excessive malpractice awards, that the awards are made up of components that, from a policy standpoint, raise different issues and probably demand different treatment.

Product liability litigation, although of smaller economic concern to health care providers, raises major issues of hidden costs, both financial and social: high-risk but valuable products that are kept from the market because, when the threat of liability is factored in, the estimated cost of developing and marketing the product is too high in relation to the profit it might be expected to generate.

Litigation to terminate health care would not ordinarily affect the base price of services (again, subject to issues of supply and demand). On the whole, it should be expected to act, perhaps increasingly, as some offset to the rising costs associated with the use of ever more sophisticated equipment developed to prolong life in ever less hopeful circumstances.

Antitrust litigation interferes with efficiencies in service delivery that could reduce both the base price of services and the costs of the health care system. But it also interferes with market concentration that, arguably, would increase those prices and costs. Where the balance lies remains finally to be determined.